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HANTS. EXAMINER

25M1/0715

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ART UNIT PAPER NUMBER

2505

12

DATE MAILED: 07/15/94

07/15/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

#12

This application has been examined Responsive to communication filed on 3/30/94 This action is made final.
A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Art Cited by Applicant, PTO-1449.
3. Information on How to Effect Drawing Changes, PTO-1474.
2. Notice re Patent Drawing, PTO-948.
4. Notice of Informal Patent Application, Form PTO-152.
6. _____

Part II SUMMARY OF ACTIONS

1. Claims 1-36 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 1-36 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner. disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed on _____, has been approved. disapproved (see explanation).

12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____

11 *other*

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MPEP 2001.06(b))

Applicant in the amendment of March 30, 1994 (paper #10) has informed the Examiner that the instant applications is a continuation-in-part of serial number 07/313,919 filed February 23, 1989, now abandoned. The following is taken from MPEP 2001.06(b)):

The individuals covered by 37 CFR 1.56 have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States application which are "material patentability" of the application in question. As set forth by the court in Armour & Co. v. Swift & Co., 175 USPQ 70, 79 (7th Cir. 1972),

"we think that it is unfair to the busy examiner, no matter how diligent and well informed he may be, to assume that he retains details of every pending file in his mind when he is reviewing a particular application ... [T]he applicant has the burden of presenting the examiner with a complete and accurate record to support the allowance of letters patent."

See, also >MPEP<§ 2004 at No. >9<.

Accordingly, the individuals covered by 37 CFR< 1.56 cannot assume that the examiner of a particular application is

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necessarily aware of other applications "material to patentability" of the application in question, but must instead bring such other applications to the attention of the examiner. For example, if a particular inventor has different applications pending in which similar subject matter but patentably indistinct claims are present that fact must be disclosed to the examiner of each of the involved applications. Similarly, the prior art references from one application must be made of record in another subsequent application if such prior art references are "material to patentability" of the subsequent application.

Application 07/313,919 has the same assignee and the same attorney. Since 07/313,919 contains a similar specification and the same and similar claims, Applicant should shed some light on the distinctions between 07/313,919 and the instant application, and provide information as to why 07/313,919 was not identified earlier in the instant application.

102 REJECTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed

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publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 20-24, 26-27, and 34-36 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Anderson et al.

Anderson specifically states in the abstract that the present study was made with an integrating sphere spectrometer (see Figure 1) and application of Twersky's theory for the multiple scattering of waves permitted separation of the effects of absorption and scattering and the light transmittance on nonhaemoglobin blood i.e. unaltered whole blood. It is shown that the relationship between light scattering and red-cell concentration is parabolic and that the absorption of light within the erythrocyte is the same as in a haemoglobin solution, i.e. altered whole blood. See pages 174-183 in regard to the molar extinction coefficients, and the plurality of substantially monochromatic wavelengths. Note that Anderson inherently has correction for calculated concentrations, since the results of Anderson would have no meaning without such a correction. (See page 180, last line of the first paragraph).

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103 REJECTION

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 2-9, 11-19, 25 and 28-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson.

Anderson in an unaltered whole blood measurement system, fails to disclose the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

At the time invention was made, it would have been obvious to one with ordinary skill in the art to modify Anderson to

incorporate the specifics cited above. The rationale for this modification would have arisen, since it is apparent that the depth of the sample, the detecting area, the distance from the sample, and the half aperture angle all have a specific effect on the overall-measurement and it is a matter of design engineering to select which depth, area distance, or angle is required for a particular outcome. Anderson specifically shows that for different depths, different wavelengths etc., different results occur. Thus, a specific relationship between all of the specifics cited above are well known and it is up to the person conducting the measurement what specifics are required for that specific outcome to occur. As for the error index, bilirubin, sulfhemoglobin, red blood cell scattering and non specific scattering vectors, the same reasoning cited above applies. It is up to the person conducting the measurement, as to what specifics are required for that specific outcome to occur.

In regard to claims 12-15, see page 177, second to last line of the first paragraph.

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NEW ART REJECTION-102 REJECTION

Claims 1, 10, 20-21, 23-24, 26-27 and 34-36 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Curtis et al.

Curtis discloses the following:

a) "generating .. blood;"

See column 6, lines 25+.

b) "irradiating ... blood;" See Figure 2

c) "detecting ... components"; See Figure 2

d) "calculating .. wavelengths"; See columns 4-6

Note that Curtis' system compensates for dirt, turbity of the sample, changes in the light source, scratches or other system variables which effect the absorbance output. Thus, minimization of radiation scattering are disclosed by Curtis (see columns 1-2).

NEW ART REJECTION-103 REJECTION

Claims 11-19, and 29-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Curtis.

Curtis, in an unaltered whole blood analysis system, disclose everything except selecting four radiation wavelengths.

At the time the invention was made, it would have been obvious to one with ordinary skill in the art to modify Curtis to

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incorporate the four wavelength of Applicant's device. The rationale for this modification would have arisen since Curtis selects two wavelengths so as to minimize error due to the variations in the oxygenation, deoxygenation of the blood. It would have been obvious to modify Curtis to select four wavelengths instead of two wavelengths since the four wavelengths are used for the same reasons two wavelengths are used i.e. to reduce variations as cited above. Clearly, the interchangeability of selecting two or four wavelengths is apparent since both will produce a minimum error measurement as seen by Curtis.

RES JUDICATA

Claims 1-2, 5-6, 9-21, 23-24, 26-27, and 29-36 are rejected under Res Judicata on the basis of an earlier adverse decision of the board of Appeals against the inventor on the same claim or a claim involving the same issue (See MPEP 706.03(w)).

APPICANT'S ARGUMENTS CONSIDERED

Applicant's arguments filed March 30, 1994 have been fully considered but they are not deemed to be persuasive.

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RESPONSE TO APPLICANT'S ARGUMENTS

Applicant argues that Anderson does not determine the concentration of a plurality of constituent components of unaltered whole blood of unknown composition. It is very clear from Anderson that Anderson is measuring a plurality of constituent components of unaltered whole blood of unknown composition. Yes, it is true that Anderson first measures a known composition of whole unaltered blood and creates a graph. This is a "calibration" curve. Then Anderson evaluates whole unaltered blood of unknown composition and compares this to the calibration curve. Thus, Anderson, using all the steps or parts of Applicant's claims above, measures the unknown composition of whole unaltered blood.

The rejection of claims 1-33 still stand for the reasons cited above.

DECLARATIONS UNDER 37 CFR 1.132

The declarations of Mr. Schmitt and Mr. Pittman under 37 CFR 1.132 have been considered but deemed mute since they argue that the curve-fitting techniques of Anderson are different from Applicants' device where these differences of techniques are not

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claimed in Applicant's claims.

Any inquiry concerning this communication should be directed to K. Hantis at telephone number (703) 308-4801.

K.H.
Hantis/tj
July 12, 1994

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